OUTCOMES OF US FOOD REGULATION: ASSESSING THE EVIDENCE OF PUBLIC HEALTH PROTECTION

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ABSTRACT

Outcomes of US Food Regulation: Assessing the Evidence of Public Health Protection

(Under the Direction of Lori Evarts)

Food is a ubiquitous necessity. Not surprisingly, government has sought to ensure a safe and healthy food supply by imposing legal duties for both the purity and nutrition of food on the market. Lacking, however, is a comprehensive examination of these efforts to determine if they are effective in promoting positive population health outcomes. To answer this question, a systematic review was performed to identify literature which documented the measure of a public health outcome of food regulation. Fifteen studies from 1996 to April 2016 were identified which reported results of local, state, or federal food regulation using a variety of methodologies. While several studies support nutritional labeling of packaged and prepared foods, the support for efficacy of food safety regulation is limited. Further study is needed to evaluate the US food safety regulatory regime and ensure government efforts support desired public health outcomes.

KEYWORDS: Food Safety, Administrative Law, Regulation, Public Health Law, Public Health Outcomes, Nutrition

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LIST OF ABBREVIATIONS

CBO.....Congressional Budget Office

CDC.....Centers for Disease Control and Prevention

CFR .....Code of Federal Regulations

FDA.....Food and Drug Administration

FSIS.....Food Safety Inspection Service, USDA

FSMA .....Food Safety and Modernization Act

HACCP .....Hazard Analysis and Critical Control Point

HHS.....United States Department of Health and Human Services

IOM .....United States Institute of Medicine

LM .....*Listeria monocytogenes*

MeSH.....*Medical Subject Headings*

NC Gen. Stat. .....North Carolina General Statutes

NIH .....National Institutes of Health

NLEA.....Nutrition Labeling and Education Act

NLM.....National Library of Medicine

NTD.....Neural Tube Defect

OECD .....Organization for Economic Cooperation and Development

RTE .....Ready-to-eat

SC Code .....South Carolina Code of Laws Revised

USC .....United States Code

USDA .....United States Department of Agriculture

Background

Introduction

Food is fundamental to life. With the population of the United States inching past 320 million (United States Census Bureau, 2016) our nation requires almost one billion meals per day, to say nothing of mid-afternoon snack breaks or queues at the local coffee shop between meals. Despite the abundance and relative safety of food in the United States compared to other nations, it does not come without risks. Foodborne illness strikes an estimated 48 million in the United States each year, resulting in some 128,000 hospitalizations, 3,000 deaths (Centers for Disease Control and Prevention (CDC), 2014) and $15.5 billion in economic burden (Hoffman, Maculloch, & Batz, 2015). Beyond acute illness, our food supply and consumption patterns can contribute to chronic disease, such as obesity and diabetes. Current estimates put the number of obese adults in the US at close to 79 million (CDC, 2015b) with an economic impact estimated at $147 billion annually (Finkelstein, Trogdon, Cohen, & Dietz, 2009).

To their credit, policymakers are not ignoring these significant issues. At the Federal level, FY2017 budget requests for food safety between the United States Departments of Agriculture (USDA) and Health and Human Services (HHS) top some $2.6 billion (United States Department of Agriculture, 2016; United States Department of Health and Human Services, 2016). Planned spending on nutrition programs (including supplemental assistance and food distribution programs) exceeds $100 billion (USDA, 2016). Both of these objectives have seen increases in budget in recent years (Congressional Budget Office (CBO), 2012; United States Food and Drug Administration (FDA), 2016d). As a part of the public health enterprise, food regulation is one tool at the disposal of government to influence the health of its citizens.

Incumbent upon those charged with this responsibility is a duty to evaluate the public health impact. In furtherance of such a goal, a systematic review was undertaken to determine what evidence exists to support the impact of food regulation on public health outcomes.

History and Legal Foundations of Food Regulation

To fully evaluate the outcomes of food regulation, it is helpful to have some understanding of the social and legal history of government involvement in the food supply. Fundamentally, regulation is a response to the inability of a free market to effectively resolve a particular problem (Bressman, Rubin, & Stack, 2010). Food laws are among the first examples of consumer protection statutes in the United States, with some dating prior to American Independence (Hutt, Merrill, & Grossman, 2014). Indeed, until the 1970s, food and drug law represented the majority of federal regulation in the realm of health and safety (Viscusi, Vernon, & Harrington Jr, 1996).

Prior to the first legislative attention on food safety or quality in the early 20th century, common foodborne illnesses included tuberculosis, botulism, and typhoid fever ("Achievements in Public Health, 1900-1999: Safer and Healthier Foods," 1999). The first federal attempt at controlling the safety of food came in 1906 (Pure Food and Drugs Act and Meat Inspection Act) (FDA, 2014b). Following a period of limited success due to the considerable burden to prove a product dangerous, Congress passed the landmark Federal Food, Drug, and Cosmetic Act of 1938 (FDA, 2014b). This statute created many of the requirements we take for granted now: the requirement that food must be safe and “wholesome”, provision for a variety of legal remedies for violations, authorization of inspection of manufacturing facilities and establishment of labeling and quality standards. The food safety landscape remained largely

unchanged for the next 75 years until the passage of the Food Safety Modernization Act (FSMA) in 2010 (FDA, 2014b). FSMA changed the landscape from one of reactionary regulation to a system based on prevention and improved surveillance (CDC, 2015a).

The foundation of Federal regulation is the Commerce Clause of the Constitution, granting the federal government the authority to “regulate commerce with foreign nations, among the Several States…” (Grad, 2005; "US Const., Art. I, Sec. 8,"). The Federal Food, Drug and Cosmetic Act serves as both a civil and criminal statute and creates responsibilities for the safety, wholesomeness, and labeling of food and drug products ("Federal Food, Drug and Cosmetic Act," 2016). Supreme Court precedent places a premium upon consumer protection and stresses the role of the purveyor in ensuring safety:

> Such legislation dispenses with the conventional requirement for criminal conduct -- awareness of some wrongdoing. In the interest of the larger good, it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. ("United States v. Dotterweich," 1943)

This succinctly summarizes the power imbalance that exists between food sellers and consumers—members of the public would be hard pressed to determine if a food product was wholesome or its nutritional value accurately represented, making market-based solutions impractical. Instead, a regulatory system can assist in leveling what would otherwise be an unbalanced power and negotiating dynamic (Bressman et al., 2010). Since the consequences of a lack of complete information can mean illness, injury or death in the context of food and drugs, there is particular interest in government inspection to enforce quality standards (Starbird, 2005). The concept that the food safety status of a particular food item is difficult to

assess features prominently in the study of food safety issues by economists (Henson & Traill, 1993; Melkonyan & Schubert, 2009; Swinbank, 1993).

States derive authority for the regulation of public health—and food by extension—through the “police power” vested with sovereign governments (Grad, 2005) as well as those powers reserved for states by the Constitution ("US Const., Amend. 10,"). States may choose to delegate authority to county or local governments, as in North Carolina with retail food inspection ("Provision of Local Public Health Services," 2016), or retain this public health responsibility as a state government function, as in South Carolina ("Department of Health and Environmental Control," 2016; "Provision of Local Public Health Services," 2016). Since federal regulation requires movement across state lines, the responsibility for food products sold or produced locally falls to states and their subdivisions. As such, state and local laws also exert an influence on the food supply. To compensate for these varied approaches at the state and local level, states are encouraged to align regulatory authorities and requirements with Federal law to provide a single national, integrated food safety system (FDA, 2016e). The adoption by states of complementary food laws permits rapid cooperation among different levels of government and can enhance the collective ability to protect consumers and public health (Burditt, 1970).

Outcomes-based Regulation

The public health enterprise is becoming more interested in utilizing evidence-based solutions (Brownson, Fielding, & Maylahn, 2009). Evaluating the results of a regulatory policy is the means by which practitioners can determine if the existing legal constructs and implementing programs are creating the intended results and improving the public’s health.

From the observations in an Organization for Economic Cooperation and Development (OECD)-commissioned paper, proper assessment of regulatory outcomes is lacking on both sides of the Atlantic (Coglianese, 2012). As noted by Brownson et al., "decisions are often based on short-term demands rather than long-term study and policy and programs are sometimes developed around anecdotal evidence" (2003, p. 3). One analysis of regulatory accountability notes that food safety regulatory regimes are generally validated by measurement of the system, rather than of the outcomes (May, 2007). With these deficiencies in mind, the status of evidence supporting the current food regulatory regime is of interest to those responsible for ensuring a safe and wholesome food supply.

Systematic Review Process

Assessing the Evidence of Outcomes to Support Regulatory Actions

At the core of this review is a simple question: does evidence exist that food regulation improves public health outcomes? The measurement of outcomes take a variety of appearances: measuring short-term outcomes (such as awareness of the availability of nutrition information), intermediate outcomes that support improved health outcomes (such as reduced presence of foodborne pathogens in food), or final distal health outcomes which establish a concrete impact on health (reduced obesity or fewer cases of foodborne illness) (United States Centers for Disease Control and Prevention, n.d.).

Many analyses of regulatory impact take the form of economic assessments of either cost-effectiveness or net benefits (Coglianese, 2012). Other economic analyses attempt to identify the "sweet spot" where the maximum benefit for the least cost can be achieved (Viscusi, Vernon, and Harrington, Jr, 1996). Assessment of outcomes can take a variety of others forms, however, including both qualitative and quantitative measures without consideration of the economic indications (Coglianese, 2012).

While the literature includes examples of systematic study of the impact of FDA regulation in the drug realm [see e.g. (Briesacher, Soumerai, Zhang, Toh, Andrade, Wagner, Shoaibi, and Gurwitz, 2013)], similar study of the impact of the food regulatory regime appears lacking. Complicating matters is the division of food regulatory authority between the USDA Food Safety Inspection Services (FSIS) (meat and meat products, poultry, processed eggs and catfish) and FDA (all other foods). Further, since much of the work of ensuring a safe and wholesome food supply occurs through action by state and local governments, focusing

exclusively on solely Federal interventions provides an incomplete picture. In the interest of completeness, this review will examine both Federal and State/Local.

Systematic Review Methodology

Inclusion Criteria

Inclusion criteria were designed to focus results on the measurement of outcomes of food regulatory policy in the United States. Due to differences in legal foundations and authorities, studies conducted on regulatory systems outside of the United States were excluded. The potential outcome measures included were: health outcomes, intermediate outcomes, and/or economic outcomes. Studies were required to be published 1996-April 2016 in English and available free to the public or at no cost via institutional subscription services. Peer-reviewed and gray literature were included. Non-peer reviewed sources were queried via constituent databases of EBSCOhost. As food law is not the primary regulatory regime controlling alcohol, tobacco, and illicit substances, these topics were excluded. Dietary supplements, while used markedly differently than food products, are deemed as food under federal law under most circumstances and so were included as within the scope of this review ("Federal Food, Drug and Cosmetic Act," 2016) . A summary of inclusion criteria is included below in Table 1.

Table 1. Study Inclusion Criteria

Topic: Food Regulation
Description of Outcome of Regulatory Policy
Published in English and available for free, no cost, and/or publicly available
Published 1996-April 2016

Peer Reviewed or gray literature acceptable
Only domestic/United States subjects
Regulation of alcohol, tobacco, and illicit substances excluded

Initial Search Queries

A modified PRISMA systematic search method was used to identify relevant articles (Liberati et al., 2009). An illustration of the identification and review process is included below in Figure 1. Initial searches were performed using three database systems: PubMed, a service of the National Library of Medicine, NIH; PubAg, a service of the National Library of Agriculture, USDA; and EBSCOhost. A complete list of collections queried is provided in Table 2. PubMed queries were structured using Medical Subject Headings (MeSH) as follows:

"Food" AND A AND B**

"Dietary Supplement" AND A AND B**

where A* and B* are MeSH categories as defined by the National Library of Medicine (National Institutes of Health/National Library of Medicine, 2016a, 2016b). Additional terms captured by MeSH headings are described in Table 3. PubAg queries were structured as follows:

"Food" AND "regulation" AND "outcomes" (All Fields)

EBSCOhost queries were structured as follows:

Boolean: "Food" AND "regulation" AND "outcomes" (All Fields)

EBSCO search expanders of "Apply Related Words" and "Apply Equivalent Subjects" were utilized to capture similar subject matter and/or synonyms. In total, initial database searches yielded 2,778 journal articles and gray literature sources (including duplicates).

Figure 1. Review Process Diagram

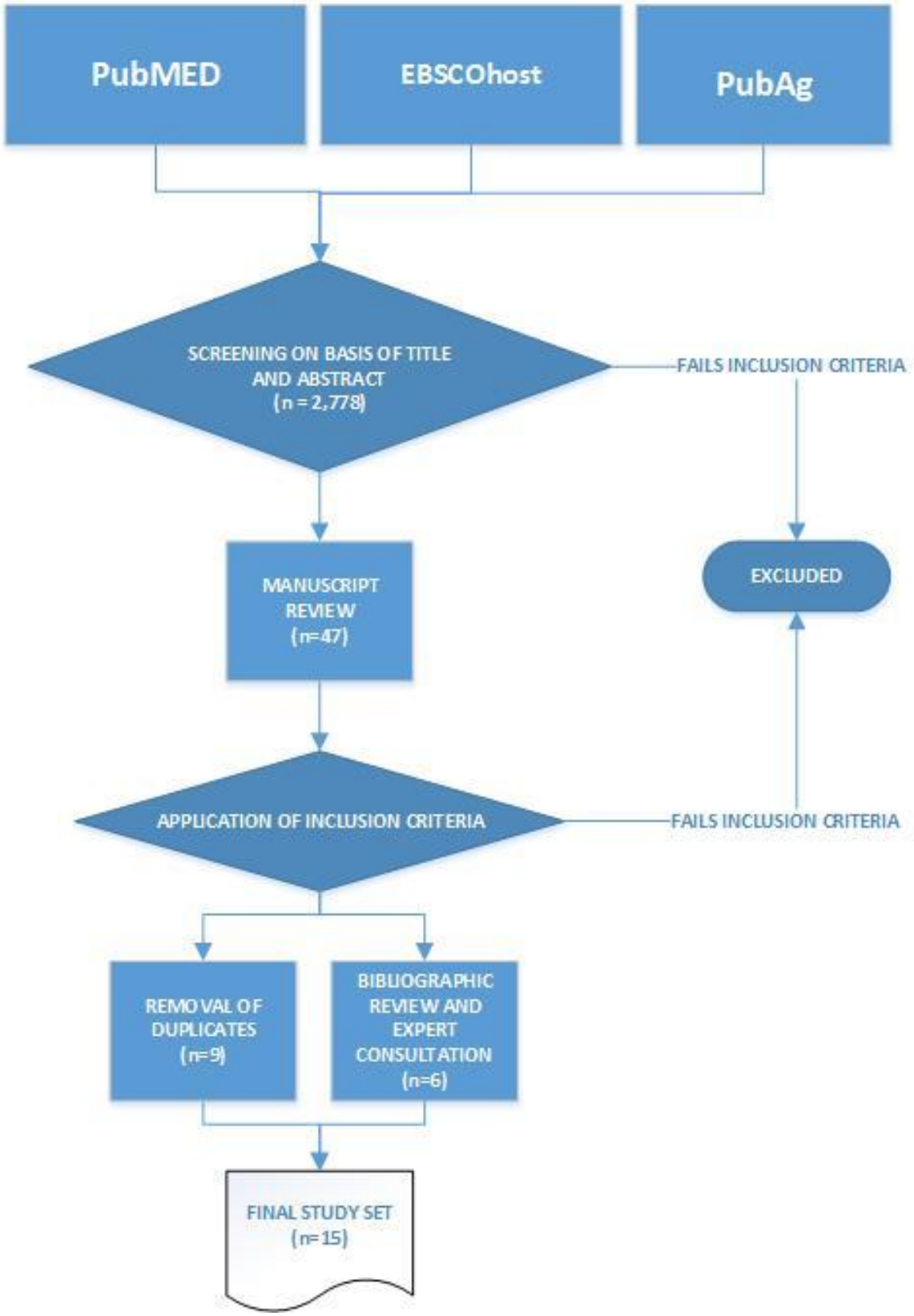

Table 2. Databases included in Search Queries

PubMed, National Library of Medicine
PubAg, National Library of Agriculture
EBSCO: Academic Search Premier
EBSCO: AHFS Consumer Medication Information
EBSCO: AMED - The Allied and Complementary Medicine Database
EBSCO: Communication & Mass Media Complete
EBSCO: CINAHL (Nursing and Allied Health)
EBSCO: EconLit
EBSCO: Education Full Text (H.W. Wilson)
EBSCO: Entrepreneurial Studies Source
EBSCO: Environment Complete
EBSCO: ERIC
EBSCO: Family & Society Studies Worldwide
EBSCO: Global Health
EBSCO: Global Health Archive
EBSCO: GreenFILE
EBSCO: Health and Psychosocial Instruments
EBSCO: Health Source - Consumer Edition
EBSCO: Health Source: Nursing/Academic Edition
EBSCO: Index to Legal Periodicals and Books (H.W. Wilson)

EBSCO: International Pharmaceutical Abstracts
EBSCO: Library & Information Science Source
EBSCO: Library
EBSCO: Information Science & Technology Abstracts with Full Text
EBSCO: Military & Government Collection
EBSCO: Newspaper Source Plus
EBSCO: Newswires
EBSCO: Regional Business News
EBSCO: Social Work Abstracts

Table 3. MeSH Terms Included in Structured PubMed Query (National Institutes of Health/National Library of Medicine, 2016a, 2016b)

A. "Social Control, Formal"	B. "Outcomes Assessment (Health Care)"
Animal Welfare	Assessment, Outcomes
Capital Punishment	Outcome Measures
Censorship, Research	Outcome Studies
Coercion	Outcomes Assessment
Government Regulation	Outcomes Research
Human Rights	
Jurisprudence	
Law Enforcement	
Legislation, Drug	
Mandatory Programs	
Patient Advocacy	
Peer Review	
Prisons	
Social Control Policies	

Screening Process

Abstracts for 2,778 initial results were reviewed and screened against inclusion criteria described in Table 1. Of these results, 47 articles were identified for further review on the basis of abstract content. Full text articles were screened against the inclusion criteria. After removal of those failing inclusion tests, nine articles were identified matching each of the inclusion requirements. Duplicate articles arising from independent queries were removed. A summary of results is included below in Table 4. Further bibliographic review and expert consultation identified a further six articles matching the inclusion criteria.

Table 4. Full-text Article Screening Results Summary

Total Full-Text Articles Screened	47
Excluded: No Outcomes Data	14
Excluded: Not USA	9
Excluded: Not Food	4
Excluded: Not Regulatory	7
Excluded: Not 1996 to April 2016	1
Included in Study (duplicates removed)	9
Bibliographic Review and Expert Consultation Additions	6
Total Articles Included	**15**

Results

In total, 15 articles were identified as meeting the criteria for inclusion. Descriptions of the studies included are below in Table 5. The identified literature falls into two broad domains of food regulation: food safety or nutrition and labeling. Peer-reviewed journal articles contributed the vast majority of those reports meeting inclusion criteria (13/15; 87%), with a single economic working paper and one magazine article also captured. The food safety and sanitation domain accounted for six studies (40%) while nutrition and labeling accounted for the remaining 60% (9/15). Somewhat unexpectedly, one-third of the studies (5/15) were contributed by economists (Bollinger, Leslie, & Sorensen, 2011; Mathios, 2000; Unnevehr & Jagmanaite, 2008; Variyam, 2008; Variyam & Cawley, 2006).

Nine articles (60%) examine Federal food policies, while six focus on state and local retail food regulation. As the FDA and USDA share Federal food regulatory authority, the agencies are combined into a single Federal Government category. Two studies focus on dietary supplements (13%). The majority of reports study an intermediate outcome (9/15; 60%) rather than a health outcome. Analytical methods include evidence of varying reliability from anecdote to epidemiologic study. Regression analysis was the most common analytical method identified (7/15; 47%).

Table 5. Summary of Results

Article	Source Type	Regulatory Domain	Level of Government	Type of Outcome	Study Population	Analytic Method	Summary of Findings
("Listeria in FSIS Ready-to-Eat Products Shows Significant Decline," 2003)	Magazine Article	Safety/Sanitation	Federal (USDA)	Intermediate Outcome (pathogen prevalence)	USDA random product samples, 1995-2003	Pre- and post-Intervention Case Study	25% reduction in detection of Listeria monocytogenes in RTE food samples after implementation of USDA intensified testing scheme
(Auchincloss et al., 2013)	Journal Article, peer reviewed	Nutrition and Labeling	State/Local	Intermediate Outcome (caloric intake)	648 fast food customers in Philadelphia, PA, August 2011	Cross-Sectional Study	Mandatory menu labeling reduces sodium, saturated fat and total caloric intake by restaurant patrons
(Bollinger, Leslie, & Sorensen, 2011)	Journal Article, peer reviewed	Nutrition and Labeling	State/Local	Intermediate Outcome (caloric intake)	Starbucks Coffee individual customer transaction records in NYC, 2008-2009	Regression Analysis	6% reduction in average calories per transaction after mandatory menu labeling

Article	Source Type	Regulatory Domain	Level of Government	Type of Outcome	Study Population	Analytic Method	Summary of Findings
(Cates et al., 2009)	Journal Article, peer reviewed	Safety/Sanitation	State/Local	Intermediate Outcome (Critical Violation Incidence)	Restaurants Inspections in Iowa, 2005-2006	Regression Analysis	Kitchen manager certifications reduce the incidence of critical violations associated with foodborne illness
(Chen et al., 2015)	Journal Article, peer reviewed	Nutrition and Labeling	State/Local	Intermediate Outcome (caloric menu labeling awareness)	3,132 Behavioral Risk Factor Surveillance System responses in King County, WA, 2008-2010	Regression Analysis	Consumer use of nutritional information increased after mandatory menu labeling
(Chui, Webb, Russell, & Naumova, 2009)	Journal Article, peer reviewed	Safety/Sanitation	Federal (USDA)	Health Outcome (Salmonella-related hospitalization)	Medicare records of hospitalization due to Salmonella, 1991-2004	Regression Analysis	Post-HACCP Regulation hospitalization trends varied by US region; results not conclusive
(Cohen, Benner, & McCormick, 2012)	Journal Article, peer reviewed	Safety/Sanitation	Federal (FDA)	Intermediate Outcome (recall effectiveness)	565 Brazilian-born women in Massachusetts, 2010	Case-Control Study	FDA recall of adulterated dietary supplement did not reduce use of product; majority of purchases by subjects occurred after recall
(Cruz, Katz, & Suarez, 2001)	Journal Article, peer reviewed	Safety/Sanitation	State/Local	Health Outcome (Outbreaks of foodborne disease)	Miami-Dade County, FL Restaurant Inspections, 1995	Case-Control Study	Food safety Inspection violations did not effectively predict restaurants responsible for foodborne outbreaks

Article	Source Type	Regulatory Domain	Level of Government	Type of Outcome	Study Population	Analytic Method	Summary of Findings
(Elbel, Kersh, Brescoll, & Dixon, 2009)	Journal Article, peer reviewed	Nutrition and Labeling	State/Local	Intermediate Outcome (caloric intake)	1,156 adults at fast food restaurants in low-income neighborhoods, Newark, NJ and NYC, 2008	Pre- and Post-intervention Street-intercept survey	No change in caloric content of food purchases after mandatory menu labeling enacted
(Grosse, Waitzman, Romano, & Mulinare, 2005)	Journal Article, peer reviewed	Nutrition and Labeling	Federal (FDA)	Health Outcome (Prevention of Neural Tube Defects)	Economic analyses by FDA, CDC, and State of California, 1991-1993	Economic Cost-Benefit Analysis	FDA requirement for folic acid-enrichment of cereal grain products associated with annual economic benefit of $312-425 million and 20-30% reductions in NTD
(Mathios, 2000)	Journal Article, peer reviewed	Nutrition and Labeling	Federal (FDA)	Intermediate Outcome (product selection)	Bottled salad dressing labels and sales in a New York State grocery chain, 1992-1995	Regression Analysis	Sales of higher-fat salad dressings fell once mandatory nutrition disclosures went into effect
(Siano, 2014)	Journal Article, peer reviewed	Safety/Sanitation	Federal (FDA)	Health Outcome (Renal Disease)	Single 26-year old male case patient, Honolulu, HI	Case Study	Consumer harm as a result of lack of effective FDA regulation of dietary supplements

Article	Source Type	Regulatory Domain	Level of Government	Type of Outcome	Study Population	Analytic Method	Summary of Findings
(Unnevehr & Jagmanaite, 2008)	Journal Article, peer reviewed	Nutrition and Labeling	Federal (FDA)	Intermediate Outcome (Product Formulation)	Labeling and formulation of 1,197 food products first marketed 2004-2006	Case Study	Increase in products reformulated to exclude trans fats after requirement for disclosure in nutrition facts
(Variyam & Cawley, 2006)	Working Paper, peer reviewed	Nutrition and Labeling	Federal (FDA and USDA)	Health Outcome (BMI)	National Health Interview Survey data, 1991-1998	Regression Analysis	Mandatory nutrition labeling reduces obesity and generates $63-166 billion in monetary benefits over 20 years
(Variyam, 2008)	Journal Article, peer reviewed	Nutrition and Labeling	Federal (FDA and USDA)	Intermediate Outcome (nutrient intake)	USDA Continuing Survey of Food Intakes by Individuals, 1994-1996	Regression Analysis	Utilization of nutritional labels results in increased consumption of fiber and iron

Discussion

Labeling and Disclosure Interventions

With the passage of the Nutrition Labeling and Education Act (NLEA) in 1990, packaged foods (save for certain classes of exemption, e.g. very small businesses or raw produce items) are required to display nutrition facts accurately disclosing the caloric and nutrient contents of the product (Mathios, 2000). Labeling regulations do not proscribe certain ingredients or food formulations, but rather require that consumers are provided an accurate picture of the nutritional content and composition of a food product. Four studies identified in the review report positive public health outcomes of nutritional disclosures—an increase in consumption of key vitamins and minerals, a reduction of BMI and savings from obesity prevention, shifts in buying patterns to products lower in fat, and industry formulation changes to exclude trans fats (Mathios, 2000; Unnevehr & Jagmanaite, 2008; Variyam, 2008; Variyam & Cawley, 2006). This collection of intermediate and distal health outcomes as measured from different populations via different analytical techniques makes a strong argument for the public health benefit of mandatory nutritional labeling.

For most of the 1990s and 2000s, nutritional labeling was confined to these same manufactured foods and remained relatively unchanged save for the addition of trans fat disclosure (Unnevehr & Jagmanaite, 2008). Over time, however, localities concerned about the nutritional impact of prepared foods purchased at retail began requiring menu labeling of nutritional content (Chen et al., 2015; Elbel, Kersh, Brescoll, & Dixon, 2009). The Affordable Care Act of 2010 directed the Food and Drug Administration to promulgate regulations for the mandatory calorie labeling of menus at restaurants with 20 or more locations. These

regulations have been added to the food labeling provisions of 21 CFR 101 (FDA, 2014a). While restaurant menu labeling has previously been exclusively the province of state and local governments, the pending rules will take this requirement nationwide. The findings of Elbel et al. notwithstanding, two other studies demonstrated retail disclosures reduced consumption of fat, sodium, and/or calories (Auchincloss et al., 2013; Bollinger et al., 2011). In total, eight of nine nutrition and labeling studies find some effect from labeling and disclosure interventions.

Food Additive Nutrition Policy

Folic acid enrichment is permitted as a food additive in many grain products and is required by standard of identity for grain products labeled as "enriched" (FDA, 2016b; FDA, United States Food and Drug Administration, 2016c). As shown by Grosse et al., the inclusion of folic acid in a standard of identity for a major staple of the American diet prevents a number of neural tube birth defects and generates a monetary benefit for the United States by reducing the economic impact of nutritionally-mediated pathology (2005). While this represents a single study covering a lone nutrient, it suggests requiring the addition of other nutrients where a clear biological mechanism supporting supplementation is known may provide a benefit to public health.

Safety and Sanitation Effectiveness

Particularly in light of the interest and findings of research related to nutritional policy, the paucity of both studies and evidence of effect of food safety regulations is notable. Two of the six studies relating to food safety address regulatory activities of the Food Safety and Inspection Service of USDA, focusing strictly on the portion of the food supply made up by meat, poultry or processed egg products (USDA, 2013). One report, a gray literature article

based on a press release from USDA, notes the reduction in food products found contaminated with *Listeria monocytogenes* (LM) after the implementation of an FSIS sampling initiative to detect LM in Ready-to-Eat (RTE) foods ("Listeria in FSIS Ready-to-Eat Products Shows Significant Decline," 2003). The other, looking at hospitalizations for Salmonella after the implementation of mandatory Hazard Analysis and Critical Control Point (HACCP) for meat and poultry products, fails to find any systematic reduction in morbidity (Chui, Webb, Russell, & Naumova, 2009). This study represents the sole study identified that attempts to measure the impact of a food safety regulation on a population-level health outcome.

FSIS regulation of meat products differs from FDA in that FSIS inspection personnel are resident in the establishment and provide continuous monitoring of manufacturing (USDA, 2013). No studies were identified that attempt to similarly evaluate the impact of FDA Good Manufacturing Practices or the implementation of HACCP programs for seafood or juice. This represents a significant gap in the literature which needs to be filled, particularly because the FDA regulatory system covers more than 80% of the US food supply (FDA, 2011). Better data on the efficacy of manufactured food safety rules would permit USDA and FDA to better protect the US food supply.

Two studies address regulation of retail food preparation, an activity typically regulated by county, state, tribal, or local government. Controls at the retail level are significant as over half of foodborne illnesses are estimated to be attributable to exposures at retail food establishments (Gould, Rosenblum, Nicholas, Phan, & Jones, 2013). The study by Cates et al. appears to indicate that mandatory training of managers at food establishments reduces the occurrence of critical violations (2009). Critical violations are those that have been established

by previous research to have a greater likelihood of causing illness or injury (FDA, 2005), and so a regulatory intervention that reduces these violations could reasonably be expected to reduce the burden of foodborne illness. In contrast, however, one study examining inspectional results and foodborne illness incidence over a one-year period in Miami-Dade County, Florida did not find that regulatory violations correlated with foodborne outbreaks (Cruz, Katz, & Suarez, 2001)[1]. The impact of retail food regulation presents a problem given the variations between jurisdictions throughout the United States. The FDA Food Code, in part, attempts to minimize this variation by providing a science-based model regulation for retail food safety (FDA, 2013). Provided a uniform system of regulation, the tracking and trending of violations provides a fertile source of data on the state of regulated industry, from trends in warning letters against manufacturing establishments to patterns of critical violations in the retail food sector. These patterns can both inform where industry should invest resources as well as direct government and academic educational resources to the most pressing need.

Of note, the two studies related to dietary supplements both describe outcomes related to ineffective regulation of herbal products. In one, the lack of effective regulation is noted in a case study which permitted an injurious supplement to be legally marketed (Siano, 2014). In the other, a product identified as adulterated with an undeclared drug ingredient was the subject of an ultimately ineffective recall and public warning (Cohen, Benner, & McCormick, 2012). While these reports are narrow and provide little indication of the effectiveness of supplement regulation more generally, these may serve as a signal that public health is not being

[1] There is a single study (Irwin, Ballard, Grendon, & Kobayashi, 1989) in the literature that does suggest retail inspection violations can be predictive of illness outbreaks. This study, however, did not fall within the inclusion criteria of this review due to its year of publication.

adequately protected by the supplement regulatory regime. Currently, however, the FDA is limited in what further actions it may take by the Dietary Supplement Health and Education Act (FDA, 2016a).

Conclusions

This review examined reports of outcomes associated with the imposition of legal controls on the manufacture and sale of food products in the United States. The food supply is fundamental to health, both in its ability to sustain and nourish and its potential to contribute to both acute and chronic disease. Regulation, as seen here, can be concerned with the inside of the package (safety) or the outside (labeling and ingredient disclosure).

Taken collectively, the studies reviewed make a case that nutrition labeling in both the packaged and prepared food contexts drive consumers to make healthier decisions and thus promote improved public health. Interestingly, these regulations only require disclosure rather than impose any substantive protections related to nutrition (the mandatory nature of labeling provisions for sellers notwithstanding).

The results for research into the outcomes of regulation for safety, however, are less certain. For a body of public health law in force for over a century, it is somewhat surprising that more does not exist on the impact of food safety controls. Rather than being an indictment, though, this is a call for further research. As the food safety community strives to reduce the burden of foodborne illness, conducting meaningful assessments of the fruits of those efforts can identify what works and what does not. Resources can be allocated to successful programs and away from those that do not show value—but first we must measure and evaluate.

Public Health Leadership in Regulatory Practice

It is in addressing this data gap that public health leadership might be effectively leveraged. There is work to be done across each of the core functions of public health (United States Institute of Medicine (IOM), 1988): better assessment to measure food-related outcomes and their antecedents, policy development to close gaps and improve regulation to reflect performance-based measures, and assurance to continually monitor the impact these changes have on population health. We need only the will and the leadership to move towards this vision.

In Frieden's model of public health interventions, changing the context of health choices to promote healthy decisions is second only to socioeconomic factors as having the broadest societal impact for the least individual effort (2010). It is in this category that food regulation lies, whether ensuring safe food or promoting nutritional choices that support good health. If implemented correctly, an opportunity exists to cost-effectively prevent illness and promote healthy decisions.

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